Title： A Clinical Study on the Feasibility and Safety of Abdominal Endoscopic Single-port Surgery System to Assist Gynecological Day Surgery

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New Technology and New Project Informed Consent Form • Notice Page

Dear Patient:

We are inviting you to participate in a new technology and new project titled “A Clinical Study on the Feasibility and Safety of Abdominal Endoscopic Single-port Surgery System to Assist Gynecological Day Surgery”.This new technology and new project has been reviewed and approved by the Medical Ethics Committee and the Medical Safety and Quality Management Committee of the Second Affiliated Hospital of Wenzhou Medical University and the Children's Hospital of Wenzhou Medical University for clinical application. Before you decide whether to participate in this new technology and new project, please read the following information carefully. It will help you understand the new technology and new project, its purpose, the procedures and duration, as well as the potential benefits, risks, and discomforts you may experience after participating. If you wish, you may also discuss with your relatives or friends, or ask the doctor for further explanation to help you make a decision.

I. What is the background of this new technology and new project?

Robotic single-port laparoscopy is a novel minimally invasive surgical method. Compared with traditional laparoscopy, it has technical advantages such as 3D visual effects, flexible micro-joints, and elimination of hand tremors, providing a good guarantee for conducting more precise, complex, and accurate surgeries. It also achieves a nearly “scarless”surgical effect, overcoming technical limitations of single-port laparoscopy such as a long learning curve, crowded instruments, and the “chopstick effect”. Although this minimally invasive method has been proven to be applicable for gynecological benign and malignant surgeries, there is currently no clear conclusion on whether robotic single-port laparoscopy is feasible and safe for gynecological day surgery. This study will collect data from 63 patients undergoing laparoscopic single-port surgery system day surgery for benign gynecological diseases at the Second Affiliated Hospital of Wenzhou Medical University to analyze the feasibility and safety of laparoscopic single-port surgery system assisted gynecological day surgery.

II. What are the inclusion and exclusion criteria for this new technology and new project?

- **Inclusion criteria**

1. Women aged 18 to 75 years old, with a body mass index (BMI) of no more than 32 kg/m2;

2. Conscious, no history of mental illness, accompanied by an adult during the perioperative

period;

3. Educate the subjects, who are willing to undergo day surgery, understand and accept the surgical method and anesthesia method;

4. Subjects and families understand perioperative care and are willing and able to complete post-discharge care;

5. Elective surgery, no serious complications affecting the operation and prognosis, aCCI age adjusted comorbidity index 0 points;

6. According to the adhesion risk scoring system of European Anti-Adhesions in Gynaecology Expert Panel (ANGEL), the adhesion risk was divided into three levels: high, medium and low. Subjects with low risk (0 to 12 points) and abdominal wall scarring and pelvic cavity B-ultrasonography do not indicate obvious pelvic cavity adhesion wiil be included.

- **Exclusion criteria**

1. Moderate and high-risk patients will be excluded based on ANGEL adhesion risk scoring system;

2. Subjects with hemorrhagic rupture of ectopic pregnancy and unstable vital signs;

3. Genital tract infection or in the acute phase of systemic infection;

4. Subjects on long-term anticoagulant therapy or with coagulation dysfunction;

5. Subjects have severe heart and lung disease, liver and kidney dysfunction, and cannot tolerate anesthesia;

6. A history of abdominal or diaphragmatic hernia, abnormal umbilical cord development, or umbilical surgery;

7. Not willing to undergo endoscopic surgery;

8. Participated in other drug and device clinical trials within 3 months before surgery.

III. What benefits may I receive if I participate in this new technology and new project?

By participating in this study, you may receive a more accurate diagnosis, although you may not directly benefit. Information obtained from this study may help others in the future.

IV. What risks, complications, or discomforts may occur if I participate in this new technology and new project? What are the preventive measures for risks and complications?

Risks during surgery: Heavy adhesions, excessive bleeding, or the need to switch to open surgery; hypercapnia, air embolism, subcutaneous, retroperitoneal emphysema, hematoma; other unforeseeable accidents and complications may occur. Risks after surgery: Intestinal adhesion, intestinal obstruction, deep vein thrombosis, pulmonary embolism; postoperative bleeding requiring secondary surgery; wound dehiscence, wound infection, incisional hernia; shoulder pain; other unforeseeable accidents and complications may occur.

Preventive measures: Strict selection of participants according to the inclusion and exclusion criteria before surgery, re-evaluation by the anesthesiologist before surgery, close monitoring of vital signs during surgery, regular outpatient follow-up after surgery to monitor wound and other postoperative outcomes, and corresponding medical treatment provided by the responsible medical team if postoperative complications occur.

V. Are there other treatment options available if I do not participate in this new technology and new project?

You may choose to undergo surgery using traditional laparoscopy.

VI. Will my personal information be kept confidential if I participate in this new technology and new project?

We will make every effort to protect your personal medical information within the limits of the law. Your medical records (medical history, laboratory test reports, etc.) will be completely stored in the hospital, and your pathological specimens will be stored in the hospital pathology department according to regulations. Your medical information will not be disclosed to other individuals or groups unless you consent. Any public reports related to this new technology and new project will not disclose your personal identity.

Necessarily, professional academic committees, ethics committees, and health supervision departments may review your medical records according to regulations. However, without permission, they will not use your medical records for other purposes or disclose them to other groups.

VII. Is it mandatory to participate in this new technology and new project?

No, participation in this new technology and new project is voluntary. You may refuse to participate in this new technology and new project, or you may withdraw at any time without facing discrimination or retaliation, and your medical treatment and rights will not be affected. You may discuss with your family or friends before making a decision.

The doctor may decide to withdraw you from the study without your consent if any of the following situations occur:

- You do not follow the doctor's instructions;

- The doctor believes that the technology/project cannot provide you with the greatest benefit;
- Other doctors believe there is a reason for you to withdraw.

VIII. Who should I contact if I have any questions?

If you have any questions about this project, please contact (name of the doctor or relevant personnel). Contact phone number:_____.

If you have any questions about your rights in participating in this project or any dissatisfaction, please contact:

Ethics Committee Name: Medical Ethics Committee of the Second Affiliated Hospital of Wenzhou Medical University and Yuying Children's Hospital Affiliated to Wenzhou Medical University

Informed Consent Form - Signature Page

Patient's Declaration

I have read the above information about this new technology and new project and have had the opportunity to discuss it with the doctor and ask questions. All my questions have been satisfactorily answered.

I understand the potential risks and benefits of participating in this new technology and new project. I am aware that participation is voluntary. I confirm that I have had sufficient time to consider this and understand that:

I can consult the doctor for more information at any time.

I can withdraw from the new technology and new project before diagnosis or treatment begins without facing discrimination or retaliation, and my medical treatment and benefits will not be affected.

I also understand that if I withdraw from the new technology and new project midway, especially if I withdraw due to treatment reasons, it will be beneficial for me to inform the doctor of any changes in my condition and to complete the corresponding physical examination and laboratory tests.

If I need to take any other medications due to changes in my condition, I will seek the doctor's advice in advance or inform the doctor truthfully afterward.

I agree that health management and supervision departments, ethics committees, or professional academic committees may review my clinical data.

Patient's Signature: _____

Signature Date: ___ Year ___Month ___ Day Contact Phone Number:_____

Patient's Legal Representative's Signature:_____ Relationship to Patient:_____

Signature Date: ___ Year ___Month ___ Day Contact Phone Number:_____

Doctor's Declaration

I confirm that I have explained the details of this new technology and new project to the patient, including their rights and potential benefits and risks.

Doctor's Signature: _____

Signature Date: ___ Year ___Month ___ Day Contact Phone Number:_____